

REMARKS

In the current Office Action, the examiner has allowed Claims 1-14 and has rejected Claims 16 and 28 under 35 USC § 112, first paragraph, as lacking enablement. The examiner has also asked for a new Abstract, as the original Abstract was not included with the application.

In this response, Claim 28 is cancelled. The rejection of Claim 16 is traversed, as explained below. Claims 15 and 17-27 were previously cancelled.

A new Abstract is enclosed as a separate page 3 of this response. This is the abstract that was part of the original application and appears on the cover page of the PCT application. The abstract was apparently separated from the application when the PCT Request was filed.

The enclosed abstract is completely supported by the information in the Field of the Invention section (page 1, lines 6-12) and the structure which appears as Formula I on page 5, line 23.

Rejection of Claim 16

The examiner has rejected Claim 16, stating that there is no teaching in the prior art that structurally similar compounds having PPAR-alpha agonist activity have therapeutic utility in treating lipid disorders. The examiner also states that there is no teaching in the specification that the claimed compounds are effective in any of the assays provided in the application.

First with respect to the assays, it is clearly stated in the paragraph from page 4, line 34 to page 5, line 6, that the compounds are potent PPAR-alpha agonists that are selective for PPAR-alpha, with preferred compounds having an IC₅₀ less than 250nM in the PPAR-alpha binding assay, which is described on pages 22-23.

With respect to the statement that there are no prior art teachings of PPAR-alpha agonists having utility to treat lipid disorders, the paragraph on page 2, line 25 to page 3, line 3 states that fibric acid derivatives, including fenofibrate, are PPAR alpha ligands and/or activators and that they reduce triglycerides and increase HDL-cholesterol and have been used to treat hypertriglyceridemia and/or mixed hyperlipidemia. Effects on LDL-cholesterol and dyslipidemia were described as "inconsistent", but were not ruled out for all PPAR alpha agonists.

In further support of the claim, the package insert for Tricor® brand fenofibrate is included. This is available at the website set up by the manufacturer, Abbott Laboratories, at www.tricortablets.com where it can be accessed by clicking on "Prescribing Information". The attachment is cited on the enclosed Form 1449B/PTO.

The attachment confirms that fenofibric acid is a PPAR alpha agonist in the Clinical Pharmacology section on page 1. It also states in the Indications and Usage section at the top of page 4 that Tricor fenofibrate can be used to treat hypercholesterolemia, hypertriglyceridemia, hyperlipidemia, and dyslipidemia, and to reduce elevated LDL-C and increase HDL-C. These are the conditions treated in Claim 16. The package insert is dated November 2004 (bottom of page 8), but fenofibrate had already been available as a drug for many years before that date.

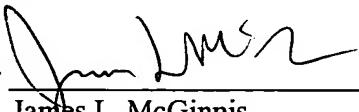
It is respectfully submitted that PPAR alpha agonists such as fenofibrate, were well known at the time the application was filed and that their utilities for treating the conditions claimed in Claim 16 were also well-known at that time. The rejection of Claim 16 should therefore be withdrawn.

Summary

The uses of the claimed compounds for the conditions listed in Claim 16 are enabled and the rejection of Claim 16 should be withdrawn.

The rejection of Claim 28 is moot because the Claim has been cancelled. A new Abstract has been submitted. The claims are therefore in condition for allowance. A Notice of Allowance is respectfully requested. If there are any matters still to be resolved, the examiner is invited to telephone the undersigned attorney at the number below.

Respectfully submitted,

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